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Developing Evidence-Based Standards for Pregnancy- Induced Hypertension in Russia

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About this series

The Case Study series presents real applications of Quality Assurance (QA) methodologies in developing countries at various health system levels, from national to community. The series focuses on QA applications in maternal and reproductive health, child survival, and infectious diseases. Each case study focuses on a major QA activity area, such as quality design, quality improvement, the development and communication of standards, and quality assessment. In some cases, more than one QA activity is presented.

Quality improvement is a systematic process of addressing the gaps between current practices and desired standards. Effective approaches to quality improvement include individual problem solving, rapid team problem solving, systematic team problem solving, and process improvement. These methods vary in the time and resources required and the number of people who participate. Regardless of the rigor and intensity of the method used, quality improvement approaches usually share four basic steps: identification of an opportunity for quality improvement, analysis of improvement area, development of possible interventions to address a need for improvement, and testing and implementation of interventions. The four-step quality improvement approach served as the basis for the methodology for clinical guideline development described in this case study; the methodology has six steps and incorporates evidence-based standards.

This case study describes how facility-level teams worked with department of health leaders in Tver Oblast, Russia, to create an evidence-based guideline as part of a larger quality improvement project to improve the system of healthcare delivery for women suffering from pregnancy-induced hypertension.


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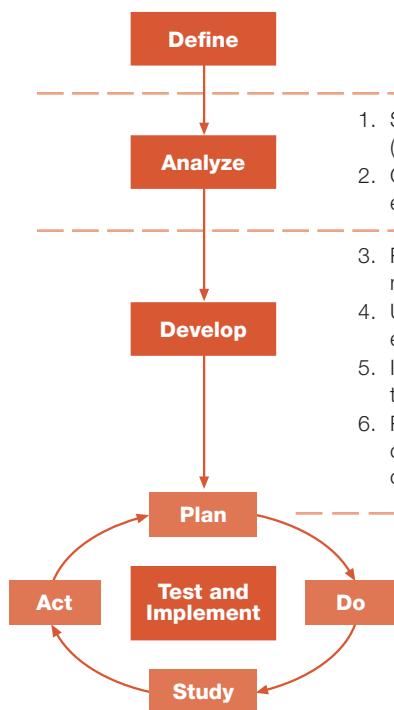
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Quality Improvement Methodology



Evidence-Based Clinical Guideline Development Methodology

1. Study the existing system of health care delivery (and create a flowchart depicting the system).
2. Clarify what clinical content knowledge is used for each step in healthcare delivery.
3. Review evidence-based literature on the subject matter of the clinical guideline.
4. Update clinical content in accordance with the evidence-based knowledge of the subject matter.
5. Introduce changes to the system of care to enable the implementation of updated content knowledge.
6. Review indicators to ensure that they reflect changes in both subject matter knowledge and changes in the system of care.



Developing Evidence-Based Standards for Pregnancy-Induced Hypertension in Russia

Background

In September 1997, the Health Committee of the United States – Russian Federation Joint Commission on Economic and Technological Cooperation decided to address

issues of access to quality healthcare as a priority area for collaboration between the two countries. The United States Agency for International Development (USAID) was asked to provide technical assistance in quality improvement. USAID responded by providing assistance through the Quality Assurance (QA) Project. In June 1998, a task force outlined the scope of work (SOW) for the access to quality healthcare priority area. The SOW included two demonstration projects in maternal child health in Tver and one in primary care in Tula. The QA Project set up demonstration projects to adapt quality improvement methods to Russian organizational culture in close collaboration with Russian and U.S. organizations, including the Ministry of Health of the Russian Federation (MOH RF), the Central Public Health Research Institute (CPHRI) of the MOH RF, Tver Oblast Department of Health, the Agency for Health Research and Quality (AHRQ), and the U.S. Department of Health and Human Services.





Tver Oblast enjoys healthier mothers and babies as a result of the new guideline.

In July 1998, a planning meeting for the demonstration projects was held with Tver Oblast Department of Health officials, including the Director of Health, the Head of Maternal and Child Health, the Head of Obstetrics/Gynecology, the Head of Neonatology, selected practicing physicians, quality improvement experts, a representative of CPHRI, and representatives of Tver State Medical Academy. A steering committee was formed later, with many of the same people, to oversee the work of the project. One goal of the planning meeting was to determine the maternal health problem most in need of improvement in Tver Oblast. Pregnancy-induced hypertension (PIH) was chosen because it was the single largest cause of maternal mortality in Tver Oblast, the major cause of complications in pregnancy, and a cause of complications in newborns. In 1997, cases of PIH occurred in 18.1 percent of all pregnancies, and the number of severe forms totaled 4.3 percent of all pregnancies; for the first six months of 1998, these figures were 16.3 percent and 3.2 percent, respectively.ⁱ On average worldwide, cases of PIH (pre-eclampsia) amount to approximately 5 percent of total pregnancies: less than one third the Tver figures.ⁱⁱ

PIH includes the conditions of pre-eclampsia and eclampsia. It can lead to maternal death and contribute to premature birth and perinatal morbidity and mortality. The diagnosis, management, and treatment of PIH were some of the most challenging clinical areas in maternal and child health facing the Tver

Oblast Department of Health. To add to the impact of PIH on the region, a large number of hospitalizations, the multitude of clinical interventions for severe forms, complicated deliveries, premature births, and neonatal rehabilitation made PIH an expensive complication in obstetrics and neonatology.

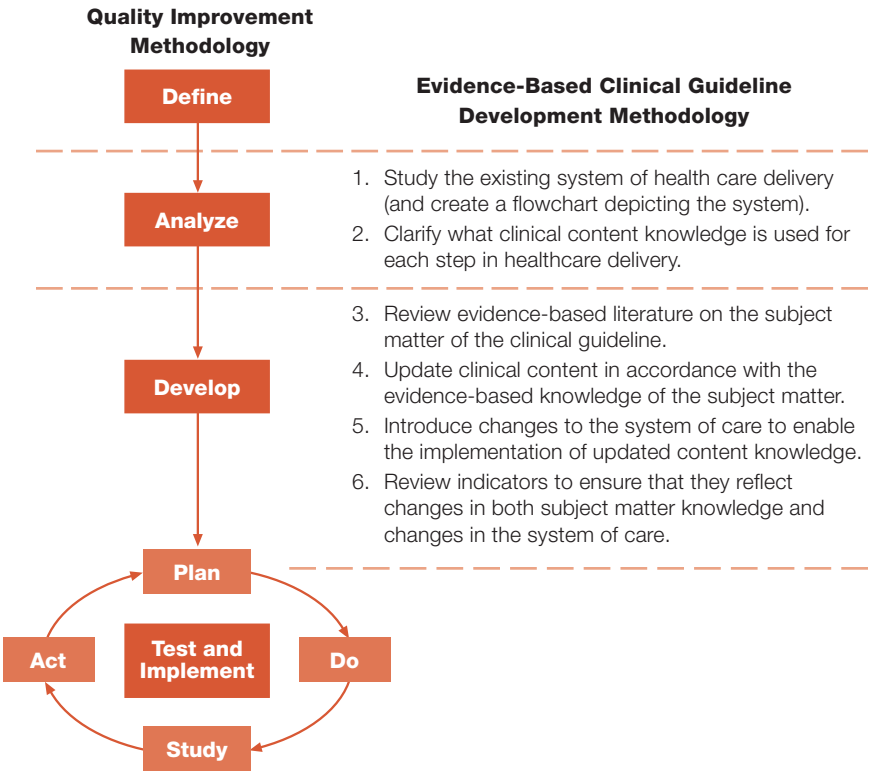
Once oblast leadership had decided on PIH as the area for improvement, they were able to choose representative facilities where the demonstration projects would take place. The three pilot facilities were Tver (city) Maternity Hospital #1, Vyshny Volochyok Maternity Hospital, and Torzhok Central District Hospital. These facilities were chosen based on their willingness to participate and represented a mix of urban and rural hospitals with a range of available resources. All three facilities include women's consultation clinics and delivery departments.

The PIH project in Tver would serve as a demonstration of how quality improvement (QI) methods can be brought together with evidence-based medicine to create changes that result in significant improvements in the healthcare delivery system and consequently in the health of the patients. One part of the overall QI effort was the development and implementation of an evidence-based clinical guideline in order to improve healthcare delivery based on a new model of PIH diagnosis, treatment, and management.

Standards Development

Methodology for clinical guideline development. The clinical and organizational guideline was developed as a key part of the improvement in the quality of care for women with PIH. While this case study focuses on the guideline development and dissemination, it must be understood within the context of the entire QI methodology used for the Quality Assurance Project in Russia. The model for this QI project was based on Batalden and Stoltz's framework for the continual improvement of healthcare,ⁱⁱⁱ which suggests the integration of clinical content knowledge and improvement knowledge as a powerful means of continual improvement in healthcare. The main principles of quality management were also applied in

Figure 1. Diagram Comparing the QI and Guideline Development Methodologies



the development of the clinical guideline. These principles are a systems approach, teamwork, customer focus, and scientific methodology. Based on this framework and the principles of quality management, Dr. Rashad Massoud of the QA Project/URC-CHS developed a six-step methodology for developing clinical guidelines as an important part of improving quality of care. (See Figure 1.)

Steps for developing clinical-organizational guidelines. A unique feature of the methodology is its integration of clinical content and the organization of care through the six steps listed on the right of Figure 1.

Some of the steps in the guideline development methodology can take place simultaneously because the clinical content of care and the organization of the healthcare system cannot be separated. The new design of the organization of care must allow for the implementation of new clinical knowledge.

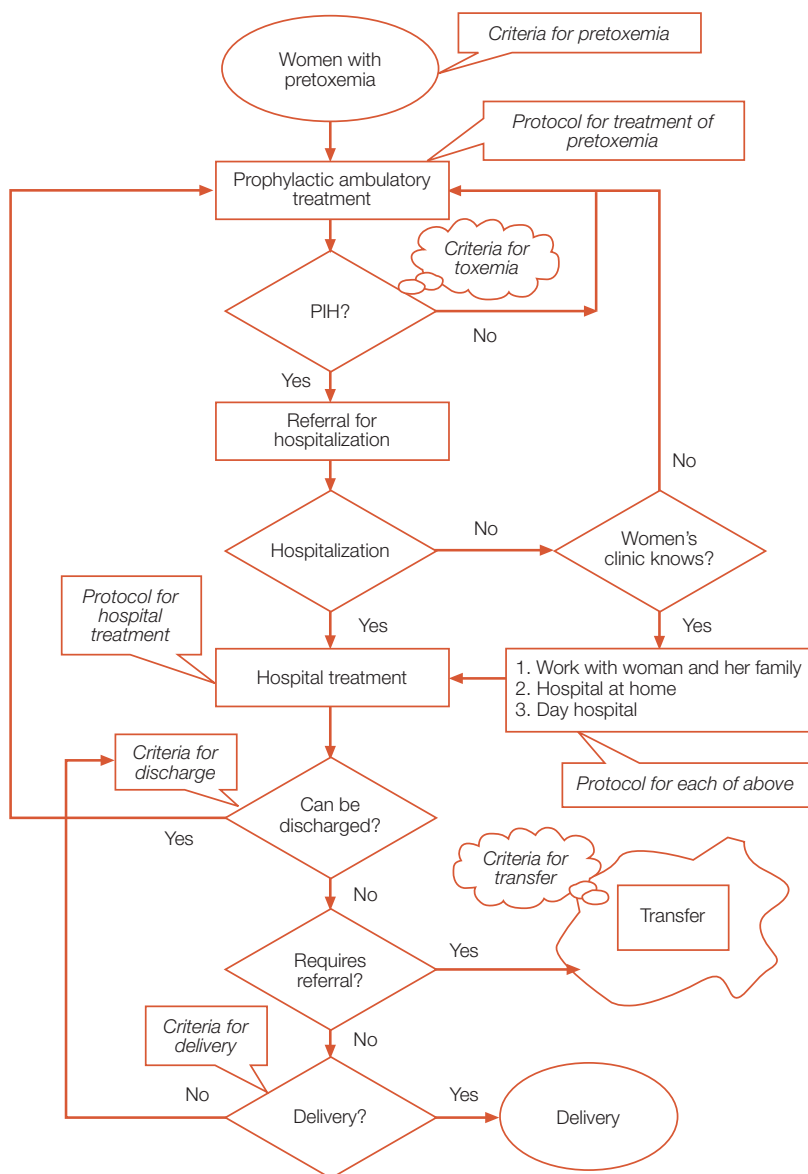
Throughout development of the guideline, Russian and U.S.-based quality assurance experts made frequent visits to the implementation sites to provide guidance and support in the QI process. The experts teamed with clinical content experts for the coaching and training process, as well as for local capacity building.

Before starting the QI project, all team members, oblast and facility leadership, and others responsible for implementation were trained in quality assurance theories and methods. Team members and oblast and facility leadership also attended training of trainers courses to learn the skills necessary to teach others the updated clinical information and QI methodology.

1. Study the Existing System of Healthcare Delivery

To begin the analysis of the current system of care, representatives from each stage of healthcare delivery for pregnant women were chosen to form a team at each pilot facility. The representatives would be primarily responsible for analyzing and improving the system of care. The facility-level teams included senior physicians, obstetrician/gynecologists, nurses and midwives, and other professionals who were in positions responsible for ensuring the implementation of changes made to clinical practice. Together these professionals provide insights on clinical content and organization for each step in the process of care. The team carefully reviewed and discussed their understanding of the organization of the system of care, which yielded a detailed flowchart (Figure 2) to illustrate the process of healthcare delivery as it was at that time.

Figure 2. “Before” Flowchart of Care for Women with Pretoxemia and Toxemia



2. Clarify Clinical Content for Each Step in Healthcare Delivery

Each facility-level team then went back through the flowchart on the process of healthcare delivery and, for each step in the process, clarified the clinical content used in making diagnoses and decisions on treatment. The clinical content included clinical definitions, criteria for diagnoses and referral, various clinical decision-making steps, and treatment guidelines. The clinical content information was listed in separate detailed appendices and referenced in the flowchart. This step allowed the team members to discover discrepancies in practice, inconsistency in decision making, and technical problems. In some cases, the process of drawing the flowchart and discussing the existing clinical practices led to small, but immediate, changes and improvements. For example, one hospital recognized the need for a standard place for all examining room equipment so that each item would be easier to find.

3. Review Evidence-Based Literature for Clinical Area

During the analysis of the current system of care, the oblast leaders, facility head physicians, and representatives of the facility-level teams reviewed the evidence-based literature in collaboration with Russian and U.S.-based clinical content experts. These individuals began to familiarize themselves with the state-of-the-art, evidence-based medicine for management of PIH from literature and information provided by the U.S. and Russian clinical experts. The international medical community has seen several significant changes in the understanding of the pathology and treatment of PIH over the last 40 years, and many of these changes have not yet been disseminated widely in Russia. Physicians and specialists in Tver, while eager to keep up with clinical advances, had limited access to state-of-the-art clinical information, reference materials, and articles due to problems of availability, language, and cost.

The system of healthcare in Russia requires physicians to follow directives and methodological recommendations from oblast health authorities and the Ministry of Health. Since the

new clinical content would require clinical practices outside of existing directives and methodological recommendations, facility teams could not make these decisions alone: they made decisions in close collaboration with Russian experts in maternal health and incorporated involvement from the Ministry of Health. This required policy dialog, reviews of clinical evidence, and debate before an agreement could be reached. The Head of Maternal Health in the MOH RF was especially helpful in approving the guideline and clinical changes at the federal level.

Deciding on clinical content to be adopted. Russian and U.S. experts in the field of obstetrics/gynecology aided the oblast leaders, head physicians, and a few members of each facility team with the decision on new and updated clinical content of the guideline by collecting evidence-based literature on PIH. The literature review for evidence-based content included both international and Russian resources on PIH. International literature was translated into Russian so that all involved in the decision-making process could review the evidence-based content. The review of clinical content incorporated several viewpoints because there is disagreement among the international community on the best diagnosis and management of PIH.

In reviewing the evidence-based literature, deciding on the clinical content, and writing the guideline, the team agreed to achieve the following:

- To create an understanding the pathophysiology of PIH
- To use international definitions
- To use internationally accepted diagnostic criteria
- To outline a treatment that was accurate (dosages, medications, frequency)
- To avoid unnecessary treatments and procedures
- To use a multidisciplinary approach

Teaching the new clinical content. Consultants held two seminars to relate the current understanding of the disease and to update physicians on best practices. Communication



*A doctor visits
a new mother
and child in
Tarzhok
Maternity
Hospital.*

of the clinical information and discussion on updating clinical content began with an initial clinical content training in January 1999. A more intensive content training was held in April 1999 with oblast leaders and facility team members who would be involved in the decision on new clinical content.

4. Update Clinical Content

Once all oblast leaders and facility teams were familiar with the evidence-based content, they needed to decide how to change their clinical practice in order to make the content compatible with the best available evidence. They first reviewed the up-to-date clinical content to decide what elements were relevant to them and what was possible to implement given the reality of their healthcare system. This step was especially difficult because of the lack of international consensus on the diagnosis and management of PIH. The oblast leaders and facility team members carefully decided on the clinical content that was supported by strong evidence, and they focused on how to implement it in local circumstances.

After the first content seminar and throughout the process, new ideas and concepts on treatment were disseminated to team members and physicians in Tver Oblast at facilities' weekly or monthly discussions. Facility team members participating in the seminars were expected to train their fellow team members and relevant personnel at their facilities in the

Table 1. ICD-10 Classification of Pregnancy-Induced Hypertension (O13-O15)

O13. Pregnancy-induced hypertension without significant proteinuria	
	Gestational hypertension NOS
	Mild pre-eclampsia
O14. Pregnancy-induced hypertension with significant proteinuria	
O14.0	Moderate pre-eclampsia
O14.1	Severe pre-eclampsia
O14.9	Pre-eclampsia, unspecified
O15. Eclampsia	
O15.0	Eclampsia in pregnancy
O15.1	Eclampsia in labor
O15.2	Eclampsia in the puerperium
O15.9	Eclampsia, unspecified as to the time period
	Eclampsia NOS

NOS: Not Otherwise Specified

state-of-the-art management of PIH. Within a few months, all staff in the pilot facilities had been trained in the updated clinical content.

Changes in clinical content. One of the first disease aspects updated in the new guideline was the name of the illness. Russian physicians had been using the term “toxemia,” which had been changed throughout the world to “pregnancy-induced hypertension.” The name change is a reflection in part of the change in the understanding of the disease pathology.

Part of the reason for high percentages of PIH among pregnant women in Tver can be attributed to diagnostic criteria, which were different than those used internationally. The criteria included a category of pre-toxemia that encompassed any woman showing signs of lower-limb edema during pregnancy.¹ The former Russian practice of care stipulated that a diagnosis of pre-toxemia due to swelling warranted

¹ Edema is swelling, and lower-limb edema is normal in many pregnant women.

Table 2. ICD-10 Diagnostic Criteria for Pregnancy Induced Hypertension (PIH) (O13-O15)

Pregnancy-induced hypertension without significant proteinuria (Mild pre-eclampsia O13)	<p>Arterial pressure \geq 140/90 mmHg but under 160/110 mmHg taken at rest at least 6 hours apart or an increase of 30 mmHg in the systolic pressure or 15 mmHg in the diastolic pressure from the baseline (baseline blood pressure documented at $<$ 16 weeks gestation)</p> <p>Proteinuria $<$ 0.3 gm or $<$ 1+</p> <p>Edema: No hand and facial edema</p>
Pregnancy-induced hypertension with significant proteinuria (Moderate pre-eclampsia O14.0.)	<p>Arterial pressure \geq 140/90 mmHg but under 160/110mmHg taken at rest at least 6 hours apart or an increase of 30 mmHg in the systolic pressure or 15 mmHg in the diastolic pressure from the baseline (baseline blood pressure documented at $<$ 16 weeks gestation)</p> <p>Proteinuria $>$ 0.3 gm but $<$ 5 gm a day or 1+ to 2+</p> <p>Edema: Hand and/or facial edema may or may not be present</p>
Pregnancy-induced hypertension with significant proteinuria (Severe pre-eclampsia O14.1)	<p>Arterial pressure \geq 160/110 mmHg taken at rest at least 6 hours apart</p> <p>Proteinuria \geq 5 gm/24 hours or 3+ to 4+</p> <p>Edema: Hand and/or facial edema may or may not be present</p>

hospitalization and intravenous treatment. The Russian and U.S. clinical specialist team determined that the International Classification of Diseases-10 (ICD-10; see Tables 1 and 2) should be used in the PIH guideline for the purposes of classification and diagnostic criteria. The updated classification and diagnostic criteria changed the Russian physicians' perception of PIH.

Table 2 outlines the diagnostic criteria adapted for the ICD-10 PIH classifications used in the clinical guideline. These criteria are based on a review of the literature and synthesis of the most current clinical recommendations used in the U.S. They help to clarify not only the diagnosis of PIH, but also the severity and risk involved for each patient.

One of the most significant changes in the approach to treating PIH in Tver Oblast was the shift to mono-therapy with intravenous magnesium sulfate (IV MgSO₄). In all, over 70 different types of medications were being used to treat women with PIH before the project in Tver. Intra-muscular magnesium sulfate was used as a prophylactic treatment for pre-eclampsia, but no evidence demonstrates its effectiveness. After much discussion between the team and content experts on the evidence-based literature and the differences in management internationally, the Tver team decided to apply mono-therapy using IV MgSO₄ treatment as prophylaxis for the prevention of eclampsia, the common practice in the U.S.

Introducing and implementing changes in the clinical content.

Implementation of these new clinical practices involved complex behavior and attitude changes. Obstetrician/gynecologists were at first skeptical of the proposed methods of treatment because it was contrary to the practices that they had been taught and were using. Other reasons for their cautious approach varied from the belief that what they were doing worked well to fear of being held responsible if complications arose. Once consensus was reached on a policy level, the physicians became more comfortable changing their practices. The numerous evidence-based articles and reference materials contributed to their confidence in trying these new methods.

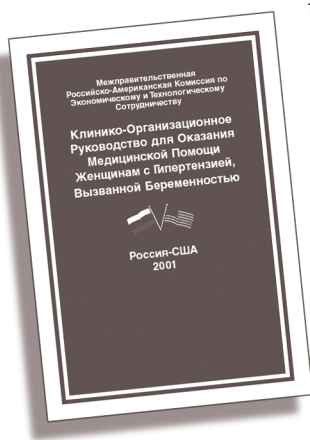
The new clinical content was introduced gradually and tested in the pilot facilities before being made into a new guideline. After a few physicians had used the new methods, more were encouraged to begin. A content expert followed up on the progress of the doctors' implementation of the new clinical content knowledge in June 1999. She found that although many of the new practices, such as mono-therapy using IV MgSO₄, were being used, treatments and dosages were not always given in accordance with the evidence-based information, which could have caused potentially serious and even fatal effects. A third clinical content seminar was held immediately for a small core group of physicians from Tver Oblast Department of Health and facility teams. The training cycle was repeated at each facility to correct and firmly incorporate

the new practices. A later follow-up visit by a clinical content expert confirmed that the third conference and subsequent trainings successfully resulted in guideline use.

5. Introduce Changes to the System of Care to Enable the Implementation of Updated Content Knowledge

The objective of this step is to decide how the system of healthcare delivery must to be changed in order to allow for the implementation of updated clinical content. Once oblast leaders and facility team members had decided on the clinical content to adopt, the teams returned to the original flowchart to decide how the system of care and current clinical practices had to be changed in order to allow for the implementation of new clinical content. A new flowchart was drawn to clearly define the updated system. At each clinical decision step, the flowchart referred to the appropriate section of ICD-10 (see Figure 5).

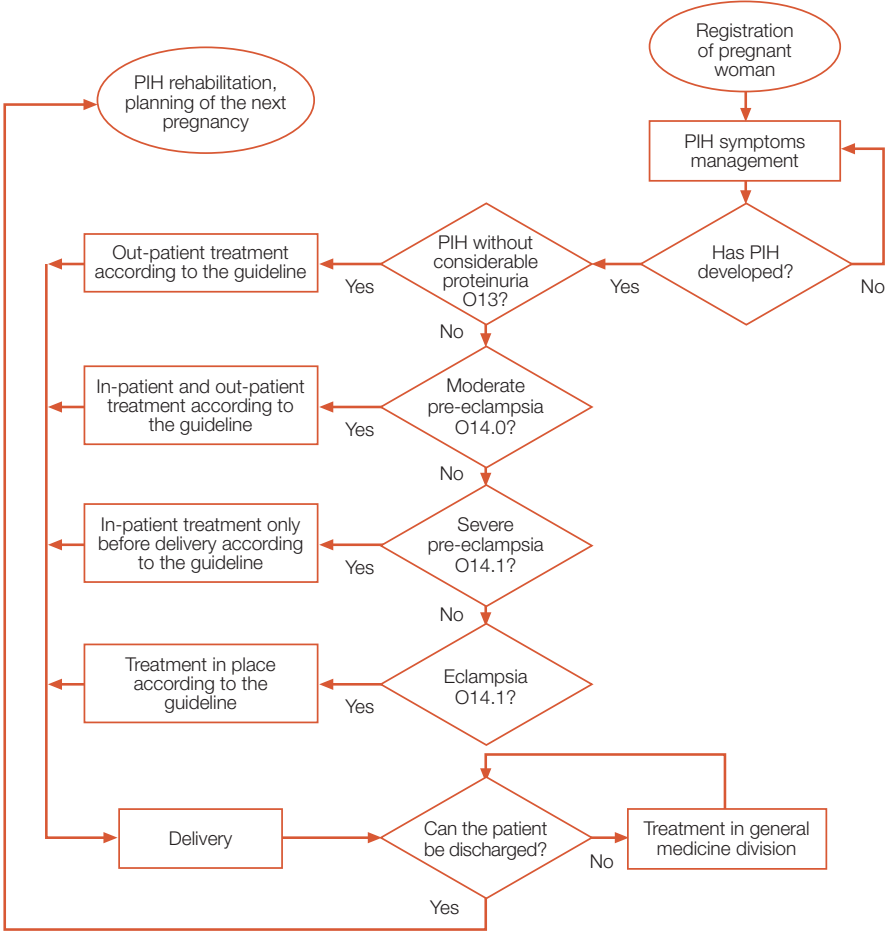
Changes in the system of care. The criteria for hospitalizing women with PIH can serve as an example of a significant change made in the system of care. Under the former system of care, the majority of women diagnosed with PIH of any severity were hospitalized for the remainder of their pregnancy. The new guideline recommends that women with mild and moderate PIH be treated on an outpatient basis through local clinics. The new system also provides education for women on necessary behavior and dietary changes as well as the warning signs of progression to a more serious condition. One result is that midwives' roles and responsibilities increased in patient follow-up and in monitoring patient conditions.



Cover of the printed version of the guideline

Writing the guideline based on changes in clinical content and organization of care. The guideline was drafted as decisions were made on changes in clinical content and the system

Figure 3. “After” Flowchart for the Process of Care for Women with PIH



of care. The writing process took several months of discussion and negotiation between the facility teams, head physicians, and Russian and U.S.-based content experts. By the end, they had agreed on a guideline that was acceptable and realizable within the Russian context, while still following state-of-the-art, evidenced-based practices. The issues that created the most discussion were:

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- Inclusion of treatments and therapies with no evidence-based proof of efficacy
 - Use of polypharmacy (multiple drugs)
 - Accuracy and clarity with regard to appropriate dosages, especially for MgSO_4

Oblast health authorities supported changes in the clinical practices in the form of a “prikaz”² (directive). The guideline was agreed upon, printed, and implemented. Several months later, another review was necessary to address oversights and clarify instructions that were revealed through clinical practice.

Official implementation of new guideline. Table 3 shows the timeline for the development of the PIH guideline. By September 1999, all three demonstration sites were using the updated clinical content, testing parts of the new system of care, and collecting data. By this time, staff at the sites recognized that the new system of care should be accepted as their way of working. Data and improvements were presented at a formal meeting for the official adoption of the guideline by the pilot sites. The Tver Oblast Department of Health signed a prikaz officially implementing the new guideline for the pilot facilities. In addition, a conference was convened with approximately 75 people, including facility administrators, head doctors, and others involved in the implementation process, in order to rally support and agreement for the program. Later in the month, the head obstetrician/gynecologist at the MOH RF sent a letter of review of the guideline and officially approved it for use in Tver Oblast in the three sites. Once the federal level issued official permission, all medical personnel involved in the project were more confident about following the new guideline.

Adoption of the new clinical-organizational guideline. As stated earlier, the new clinical practices were introduced

² Various leaders—facility, oblast department of health, or Ministry of Health officials—in the Russian healthcare system issue prikazi (directives) regarding new protocols and decisions or changes made to clinical, organizational, or administrative aspects of healthcare. Directives themselves are not new protocols or guidelines, but rather instructions to healthcare providers to begin using them.

Table 3: Timeline of Development of PIH Guideline

Date	Significant Events
June 1998	U.S./Russian Joint Commission on Economic and Technical Cooperation Health Committee “Access to Quality Healthcare” priority area Task Force Meeting
July 1998	First planning meeting and trip for QA Project staff
October 1998	First QA training for leaders
December 1998	Training of trainers
January 1999	First large content training; training for teams in Tula, Tver, and Moscow
February 1999	Organization of care workshops
April 1999	2nd Content training for small group (mainly doctors)
June 1999	Content experts check sites for use of new guideline; 3rd Content training
September 1999	Prikaz and letter from head of Maternal Health MOH RF
July 2000	Results conference
September 2000	Project scale-up begins

gradually throughout the improvement process. Although official implementation of the guideline occurred in September 1999, many aspects of the new clinical content were already being practiced.

Interestingly, the facility that adopted these changes first was not the central, urban hospital with more funding, but rather the provincial hospital in Torzhok. Tver Maternity Hospital #1 in Tver city, the last of the three pilot sites to begin using the updated guideline, was encouraged to start once they saw the small town hospital in Torzhok making improvements. Despite initial reluctance, the teams successfully developed and implemented the evidence-based clinical guideline in all three pilot sites.

Key Changes Made to the System of Care for Women with PIH in Tver

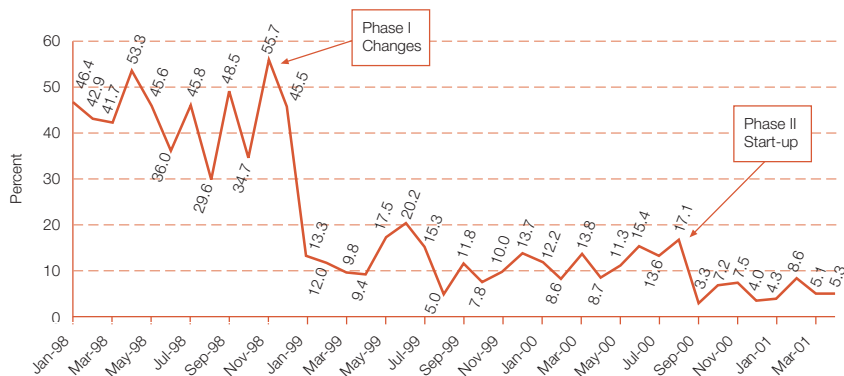
1. The new clinical guideline is based on the 10th edition of the International Classification of Diseases (ICD-10).
2. The new clinical guideline represents a significant change in the understanding of PIH; it stresses the importance of monotherapy with Mg SO_4 and early delivery.
3. The new guideline does not include old categories of pre-toxemia or require preventative hospitalization or various other non-evidence-based treatments for PIH.
4. The new guideline has promoted the role of the midwife in the management of PIH.
5. Existing “directives” and “methodological recommendations” are being changed in order to facilitate the implementation of the new system.

Revisions of the guideline. During the first year of use, it became clear that several sections of the guideline should be rewritten or clarified. A year after the implementation, international experts and Tver specialists met to discuss necessary changes and updates. A revised version was published in order to ensure patient safety, the physicians’ ability to correctly implement the guideline, and the relevance to local circumstances.

6. Review Indicators

At the start of the project, while the system of care was being studied, a set of indicators was designed based on the clinical content used at that time in the delivery of care. These indicators were based on the former classification and approach to the management of PIH. Once the new organization of the system of care was developed and new clinical content was decided upon, the indicators were revised to ensure that they reflected these changes and would ad-

Figure 4. Sample Run Chart of Results: Deliveries to Women with PIH as a Percentage of All Deliveries



equately measure improvements. For example, when the first set of indicators was created, IV Mg SO₄ was not being used: a new indicator had to be added so that the use of this treatment could be monitored.

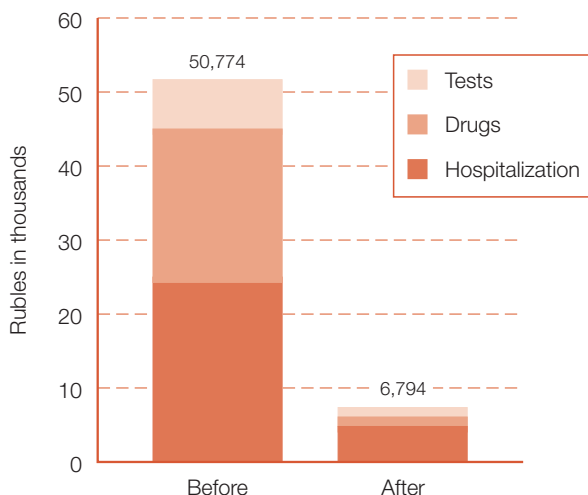
All indicators in this project were collected in three pilot sites and tracked through the use of run charts. Figure 4 is an example of one indicator: It shows the delivery to women with PIH as a percentage of all deliveries in the three pilot sites. The first arrow points to a drop that signals the introduction of the evidence-based clinical guideline in the demonstration project. The second drop came at the beginning of the scale-up as team members from demonstration sites were trained as trainers for the newly participating organizations: by virtue of their training experience, the trainers and their organizations became more proficient in the clinical content and practice, causing the drop.

Results

Clinical Results

The results from the Quality Assurance Project in Tver Oblast, such as those in Figure 4, show that the guideline is being successfully implemented in the three pilot facilities with positive results. Achievements include the appropriateness of

Figure 5. Total Cost of Care for PIH



the guideline to the local conditions, the clinical content, and the new organization. Between the implementation of the guideline clinical content in January 1999 and May 2001, there were:

- No cases of maternal death due to eclampsia
- No cases of progression to eclampsia in patients managed by the new system of PIH care
- A 77 percent reduction in the number of hospitalizations due to PIH

Economic Impact of the Evidence-Based Guideline

In parallel to the implementation of the new clinical guideline, an operations research study was conducted to measure the impact of using new guideline on the cost of hospital care for PIH.^v The study examined the effect of the new clinical practices on the cost of care, including a reduction in the number of drugs used in treatment and reductions in the length of hospital stays.



Using evidence-based medicine has reduced both medications and hospitalizations.

A before-and-after, cross-sectional study was used (six months before and after the implementation of new guideline). Data were collected by reviewing medical records for all women who were admitted with mild, moderate, or severe forms of PIH to two hospitals in the project. (Drug costs incurred by patients were assessed for one hospital.) Based on changes made in clinical practice in the new guideline, the costs of drugs, hospitalizations, and clinical tests were expected to change.

The following is a summary of some of the findings from the study:

- Overall, a cost saving of about 87 percent in the average total cost of care was observed. Reductions in the number of hospitalizations as well as in the average cost of care per patient were important drivers of cost saving (See Figure 5).
- Reduction in the total average cost of hospitalizations accounted for about 70 percent of the total cost saving. The decrease was mainly due to the drop in the number of hospitalizations as well as shorter hospital stays (79 percent drop in total patient-days or an average 13 percent drop per patient).
- The average total cost of care per patient decreased by 41 percent, from an average of 1,080 rubles per patient to 637.

- The total average costs of drugs and tests also decreased, by 95 percent and 80 percent, respectively, due to the new approach in managing and treating PIH.
- The average cost of drugs per patient decreased by 62 percent, driven largely by the reduction in the number of drug types used from 72 to 32.
- Analysis of patient costs also suggests potential cost savings for the patients: up to 66 percent per patient from drug cost savings.
- The number of drugs used to treat PIH dropped significantly: from 72 types to 32; Mg SO₄ use increased.

The change in the cost of hospital and drug care between the before and after patients contributes to the indicators that the new guideline was being followed. The findings suggest that efforts to improve quality can be accomplished while reducing costs. In addition, the evidence-based guideline for managing pregnancy-induced hypertension led to improved health outcomes for women and their newborns, suggesting that long-term cost benefits may result.

Phase II: Oblast-Wide Scale-up of PIH Guideline

Less than a year after implementation of the PIH guideline, the exceptional results of the quality improvement in the three pilot sites led to a decision to scale up the project to an oblast-wide level. Scale-up efforts include all women's consultation clinics and maternity hospitals in Tver Oblast: 42 hospitals in 37 regions. As of this writing, participants and trainers from the pilot projects are conducting most of the quality assurance training, clinical content training, and coaching. Teams at each facility are adapting the organizational aspects of the new guideline for local circumstances. Facilities and individual medical personnel have been responsive to the project and encouraged to participate by the results from Tver, Torzhok, and Vyshny Volochyok.

Standards Development and Quality Improvement Insights

■ **The Russian experience shows that guidelines created by the users are more easily implemented in the local setting.**

Clinical guidelines are often developed by experts, either from the country itself or from other countries, who have the most advanced knowledge on the subject, access to the best facilities, the newest drugs, and state-of-the-art equipment. Guidelines thus developed are difficult for practicing physicians to follow in local realities and circumstances. Working with the six-step methodology, the clinical content experts provided teams with all of the evidence-based information necessary to develop the guideline. The teams could then take the evidence-based clinical information and incorporate it into a new system of care in a way that would work in their facility and local reality. By becoming thoroughly familiar with the clinical content—rather than learning it, perhaps superficially, through a training or reading—doctors became more knowledgeable on the topic. In addition, the sense of ownership that came from developing the guideline helped alleviate some of the resistance that would have come if the guideline had been imposed in a top-down manner.

■ **Communication of standards happened simultaneously with the development of standards, since those creating the guideline were also the users, eliminating the need for a separate dissemination step.**

This method for clinical guideline development provides that the same people who design guidelines implement them, eliminating the need for a separate step for communication and dissemination. Communication of the changes in both the clinical content and organization

of the system of healthcare delivery for women with PIH was an integrated part of the QI project. Before clinical content trainings on PIH were held, team members participated in training of trainers courses to gain the skills necessary to teach others the updated clinical information and QI methodology. Team members at the training were expected to share the information with their team. From the outset of the project and the first clinical content training, the new information was passed on to health professionals in the pilot facilities through several means, such as weekly rounds and department meetings. As soon as decisions were made on changes in clinical content, and before the guideline was officially published and distributed, physicians in the pilot facilities were already managing patients with PIH according to these updated practices. This allowed for questions, clarifications, and identification of possible problems before the guideline was finalized and printed.

■ **A strategic area of importance to those working on the project should be chosen for the initial quality improvement demonstration.**

This decision must be made at the local level in order to gain the support of those responsible for implementation. In the case of Tver, international experts and Ministry of Health officials were encouraging the steering committee in Tver to choose anemia in pregnant women as the improvement area since this is a widespread problem throughout Russia. However, Tver department of health officials insisted that they wanted to undertake improvement efforts for pregnancy-induced hypertension because it was the single largest cause of maternal mortality, had high frequency in Tver Oblast, and was problematic for physicians to treat. In the end, the project strongly impacted and improved the state of PIH in Tver Oblast. Since PIH

was a critical problem, which has been significantly improved through the quality improvement project, oblast leadership as well as many facility administrators, physicians, and other medical personnel have become strong proponents of the guideline and the quality improvement methodology.



End Notes

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Developing Evidence-Based Standards for Pregnancy-Induced Hypertension in Russia: Summary

As part of a quality improvement effort in Tver Oblast, Russia, multi-disciplinary, facility-level teams and the Tver Oblast Department of Health, in close collaboration with the Quality Assurance Project and the Central Public Health Research Institute of the Ministry of Health of the Russian Federation, created and implemented a clinical/organizational guideline on the system of healthcare delivery for women with pregnancy-induced hypertension (PIH). The quality improvement project was based on a six-step methodology that combines the clinical and organizational aspects of the system of healthcare delivery for women with PIH. Teams of practicing physicians, nurses, midwives, and administrators developed the guideline as part of a larger quality improvement effort in collaboration with clinical experts who provided evidence-based clinical information. This methodology is unique in that the same people who created the guideline were responsible for implementing it, making it more functional and relevant to local realities. As a consequence, significant changes in the management of PIH and in the system of healthcare delivery for women with PIH have led to reduced maternal morbidity and mortality.